

REMARKS

Claims 1-31 are currently pending and as a result of the previous Restriction Requirement, Claims 15-28 are withdrawn from consideration as a non-elected invention. By this amendment, Claim 5 and Claim 31 (which is a substantial duplicate of Claim 4) are cancelled. According to the Office Action of March 13, 2002, the Examiner has considered only Claims 1, 2 and 5 of the elected invention, and has not considered Claims 3, 4, and 6-31 which constitute non-elected species, however these claims remain pending.

Support for the amendments to Claim 1 and the specification find support in the specification as filed, as detailed herein. Therefore no new matter is added to this application.

Amendments to Specification and Claims Reflecting Clerical Errors

The amendment to Claim 1 and the corresponding section of the specification (page 14, line 25-page 15, line 26) is as follows. First, hydrogen atoms are missing from the -ene functionalities, specifically $-\underline{\text{CH}}=\text{CH}-\text{R}$ and $-\text{R}-\underline{\text{CH}}=\text{CH}_2$, in section b of the compound description (page 15, line 9) as well as Claim 1. These clerical mistakes are corrected by this amendment. One of ordinary skill would readily recognize this clerical error from the requirement for a hydrogen atom to satisfy the valence of each carbon to which it is bonded. Additionally, a duplicate selection for R_a is $-\text{N}_3$ appears in the specification (page 15, line 9) and Claim 1, and is deleted.

The deletion of the substituent $>\text{C}=\text{N}-\text{OH}$ from the definition of "Z" in Claim 1 and in the corresponding section of the specification (page 15, 5th full paragraph,

line 23) is made to remove a redundancy in Claim 1 and the specification. Thus, Z'' may be $>C=N-OR_5$ and R_5 may be defined, among other things, as hydrogen. Therefore, removing this redundant substituent $>C=N-OH$ does not change the scope of this claim, nor add new matter.

Priority Claim

The Office Action of March 13, 2002, requires the application to contain specific reference to prior applications in the first sentence of the specification. The complete dependency of this application was incorporated by Preliminary Amendment in the Response to Restriction Requirement and Preliminary Amendment, filed November 9, 2001.

Claim Rejections under 35 U.S.C. § 102(e) in View of Sachdeva et al.

Claims 1, 2, and 5 were rejected in the Office Action of March 13, 2002, as being anticipated by U.S. Patent No. 6,054,598 to Sachdeva et al. ("Sachdeva"). It is the Examiner's position that Sachdeva discloses both 2-ethoxyestradiol (R_a is ethyl) and 2-methoxyestradiol (R_a is methyl) and anticipates these claims. Applicants traverse this rejection with respect to Claim 2, and have obviated this rejection with respect to Claims 1 and 5 as follows.

Claim 1 is amended to recite the proviso that if R_b is H, R_o is H, Z' is $>COH$, $>C-R_g$ is $>C(H)-OH$, and Z'' is $>CH_2$, then R_a is neither $-OCH_3$ nor $-OCH_2CH_3$. This proviso specifically removes both 2-methoxyestradiol and 2-ethoxyestradiol from Claim 1. Therefore, Claim 1 is not anticipated by Sachdeva.

Applicants traverse this rejection with respect to Claim 2, which defines R_a as $-C\equiv C-CH_3$. No such compound appears in Sachdeva, therefore Claim 2 is not anticipated by Sachdeva.

Finally, Claim 5, which encompasses 2-ethoxyestradiol, has been cancelled, thereby obviated this rejection with respect to Claim 5.

Applicants assert that neither Claim 1 nor Claim 2 reads on the reference species of Sachdeva. Accordingly, Applicants respectfully request removal of this rejection and allowance of these claims.

Claim Rejections under 35 U.S.C. § 102(e) in View of Nambara et al.

The Office Action of March 13, 2002 rejected Claims 1, 2 and 5 as being anticipated by DN 82:43650 (Abstract of Chem. Pharm. Bull. 1974, 22(10), 2455-7) to Nambara et al. ("Nambara"). Specifically, it is the Examiner's position that Claims 1, 2 and 5 are anticipated by compounds RN 54502-29-3 and 54502-31-7 (shown on page 14 of Nambara abstract), which constitute *R*- (α) and *S*- (β) enantiomers of 2-methoxy-3-hydroxy-16-chloro-estra-1,3,5(10)-trien-17-one. Applicants respectfully traverse this rejection with respect to Claims 1 and 2. Further, Applicants' cancellation of Claim 5 has obviated this rejection with respect to Claim 5.

Compounds RN 54502-29-3 and 54502-31-7 of Nambara (page 14) both require a 16-chloro substituent on the estra-1,3,5(10)-trien-17-one steroidal core. However, Claims 1 and 2 are directed to compounds that contain only hydrogen atoms at the C16 position. Therefore, Nambara cannot anticipate Claims 1 or 2 and accordingly,

Applicants respectfully request withdrawal of this rejection, and allowance of Claims 1 and 2.

Claim Rejections under 35 U.S.C. § 102(e) in View of D'Amato et al.

The Office Action of March 13, 2002 also rejected Claims 1, 2 and 5 as being anticipated by U.S. Patent No. 5,504,074 to D'Amato et al. ("D'Amato"). It is the Examiner's position that Claims 1, 2 and 5 are anticipated by the first two compounds of Table 2, namely, 2-methoxyestradiol and 2-methoxyestrone. The Examiner also cites Table 1, lines 32, 37, 38 and 41 (column 8) against Claims 1, 2 and 5.

Applicants note that the specific compounds of D'Amato's Table 1 to which the Examiner refers can not be determined unambiguously. However, it is Applicants' belief that the Examiner refers to the following species of Table 1: 2-methoxyestradiol, estradiol, estrone, and 2-methoxyestradiol-3-O-methylether. Applicants respectfully traverse this rejection with respect to Claims 1 and 2 as follows. Further, Applicants' cancellation of Claim 5 has obviated this rejection with respect to Claim 5.

2-Methoxyestradiol. As amended herein, Claim 1 recites the proviso that if R_b is H, R_o is H, Z' is $>COH$, $>C-R_g$ is $>C(H)-OH$, and Z'' is $>CH_2$, then R_a is neither $-OCH_3$ nor $-OCH_2CH_3$. This proviso specifically excepts 2-methoxyestradiol from Claim 1. Therefore, Claim 1 does not read on this compound in Table 1 of D'Amato.

Estradiol. This compound requires R_a to be a hydrogen atom, which is bonded to the C2 position of the steroid structure. Applicants respectfully note that

Claim 1 does not define R_a as hydrogen, therefore Claim 1 is not anticipated by this compound in Table 1 of D'Amato.

Estrone. This compound requires R_a to be a hydrogen atom, which is bonded to the C2 position of the steroid structure. Applicants respectfully note that Claim 1 does not define R_a as hydrogen, therefore Claim 1 is not anticipated by this compound in Table 1 of D'Amato.

2-Methoxyestradiol-3-O-methylether. This compound requires Z' to be $>CO-CH_3$, in which a methyl ether moiety is bonded at the C3 position of the steroid structure. Applicants respectfully note that Claim 1 does not define Z' as $>CO-CH_3$, therefore Claim 1 is not anticipated by this compound in Table 1 of D'Amato.

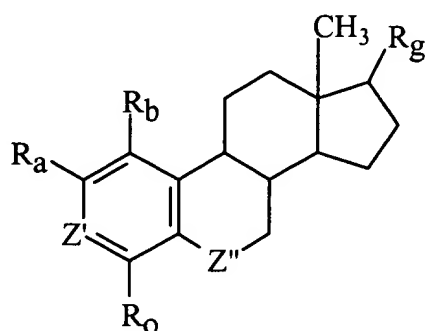
Applicants maintain that none of the cited compounds in Table 1 of D'Amato anticipate Claim 1. Accordingly, Applicants respectfully request withdrawal of this rejection, and allowance of Claims 1 and 2.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amendments in the Claims

In accordance with 37 C.F.R. § 1.121(c), the following version of the rewritten claim shows all the changes made by the foregoing amendment relative to the previous version of that claim.

1. (Amended) A compound of the general formula:



wherein:


- a) R_b and R_o are independently -H, -Cl, -Br, -I, -F, -CN, lower alkyl, -OH, -CH₂-OH, -NH₂; or N(R_6)(R_7), wherein R_6 and R_7 are independently hydrogen or an alkyl or branched alkyl with up to 6 carbons;
- b) R_a is -N₃, -C≡N, [-N₃,] -C≡C-R, -CH=CH-R, -R-CH=CH₂, -C≡CH, -O-R, -R-R₁, or -O-R-R₁ where R is a straight or branched alkyl with up to 10 carbons or aralkyl, and R_1 is -OH, -NH₂, -Cl, -Br, -I, -F or CF₃;

- c) Z' is $>CH$, $>COH$, or $>C-R_2-OH$, where R_2 is an alkyl or branched alkyl with up to 10 carbons or aralkyl;
- d) $>C-R_g$ is $>CH_2$, $>C(H)-OH$, $>C=O$, $>C=N-OH$, $>C(R_3)OH$, $>C=N-OR_3$, $>C(H)-NH_2$, $>C(H)-NHR_3$, $>C(H)-NR_3R_4$, or $>C(H)-C(O)-R_3$, where each R_3 and R_4 is independently an alkyl or branched alkyl with up to 10 carbons or aralkyl; and
- e) Z'' is $>CH_2$, $>C=O$, $>C(H)-OH$, [$>C=N-OH$,] $>C=N-OR_5$, $>C(H)-C\equiv N$, or $>C(H)-NR_5R_5$, wherein each R_5 is independently hydrogen, an alkyl or branched alkyl with up to 10 carbons or aralkyl;
- with the proviso that if R_b is H, R_o is H, Z' is $>COH$, $>C-R_g$ is $>C(H)-OH$, and Z'' is $>CH_2$, then R_a is neither $-OCH_3$ nor $-OCH_2CH_3$.

Conclusion

In view of the above amendments and remarks, Applicants aver that the claims are now in condition for allowance. Such action is respectfully requested. If there are informalities remaining in the application which may be corrected by Examiner's Amendment, or there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2413 is respectfully solicited.

Respectfully submitted,


By: David E. Wigley, Ph.D.
Reg. No. P52,362

KILPATRICK STOCKTON LLP
1100 Peachtree Street, N.E.
Suite 2800
Atlanta, Georgia 30309-4530
(404) 815-6500
Docket No. 43170-260981 (05213-0910)